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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,620	06/19/2006	Annie Bardat	0040-0168PUS1	1914

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
09/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,620	BARDAT ET AL.	
	Examiner	Art Unit	
	HOPE A. ROBINSON	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 14-18* is/are rejected.

7)☒ Claim(s) *2-13 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed December 29, 2008 on June 4, 2009 is acknowledged.

Claim Disposition

2. Claims 1-19 are pending and are under examination.

Claim Objection

3. Claims 1-19 are objected to because of the following informalities:

For clarity and precision of claim language it is suggested that claim 1 is amended to read,

" A process for obtaining a cryoprecipitable protein[[s]] comprising:

(a) contacting a composition of the crvprecipitable protein[[(s)]] of interest with a stabilizing and solubilizing formulation comprising a mixture of arginine, at least one hydrophobic amino acid and trisodium phosphate; [[and]]

(b) transforming said protein[[(s)]] composition into a freeze-dried [[form]] protein; and

(c) performing a virus inactivation step by heat treatment of said freeze-dried protein[[s]].

For clarity and consistency it is suggested that claim 2 is amended to read, "[[A]] The process [[according to]] of claim 1, [[characterized in that]] wherein the formulation consists essentially of the [[said]] mixture of arginine, [[at least one]] the hydrophobic amino acid and the trisodium phosphate.

For clarity and precision of claim language, it is suggested that claim 3 is amended to read, "[[A]] The process [[according to]] of claim 1, wherein arginine is present in a concentration of from 25 to 50 g/1".

For clarity it is suggested that claim 4 is amended to read, "[[A]] The process [[according to]] of claim 3, wherein the concentration of arginine is of from 35 to 45 g/1".

For clarity it is suggested that claim 5 is amended to read, "[[A]] The process [[according to]] of claim 1, wherein the trisodium citrate is present in a concentration of from 0.5 to about 12 g/1".

For clarity it is suggested that claim 6 is amended to read, "[[A]] The process [[according to]] of claim 1, wherein the hydrophobic amino acid is leucine, iso-leucine or a mixture thereof.

For clarity it is suggested that claim 7 is amended to read, "[[A]] The process [[according to]] of claim 6, wherein leucine, iso-leucine or a mixture thereof are present in a concentration of from 5 to 15 g/1".

For clarity it is suggested that claim 8 is amended to read, "[[A]] The process [[according to]] of claim 6, wherein the concentration of leucine or iso-leucine or mixture thereof [[is of]] from 9 to 11 g/1".

For clarity it is suggested that claim 9 is amended to read, "[[A]] The process [[according to]] of claim1, wherein the formulation of step (a) further contains glycine and/or lysine.

For clarity it is suggested that claim 10 is amended to read, "[[A]] The process [[according to]] of claim 9, wherein glycine and lysine are each present in a concentration [[of]] from 1 to 5 g/1".

For clarity it is suggested that claim 11 is amended to read, "[[A]] The process [[according to]] of claim 9, wherein each [[of these]] concentration[[s]] of glycine and lysine is [[of]] from 1.5 to 2.5 g/1".

For clarity it is suggested that claim 12 is amended to read, "[[A]] The process [[according to]] of claim 1, wherein [[the freeze-drying of]] step (b) is carried out at temperatures between -40°C and -30°C for 48 hours.

For clarity it is suggested that claim 13 is amended to read, "[[A]] The process [[according to]] of claim 1, wherein [[the heat treatment of virus inactivation off]] step (c) is carried out at temperatures between 80°C and 90°C for 72 hours.

For clarity it is suggested that claim 14 is amended to read, "[[A]] The process [[according to]] of claim 1, further comprising, prior to step (a), a least one step of virus inactivation and/or elimination from the [[said]] composition of crvoprecipitable protein[[(s)]] by solvent-detergent and/or by nanofiltration on filters of 35 nm.

Claim 15 is objected to because the claim does not further limit claim 1.

For clarity it is suggested that claim 16 is amended to read, "[[A]] The process [[according to]] of claim 1, [[characterized in that it is applicable to]] wherein said process uses at least one of the proteins selected from the group consisting of Factor VIII, von Willebrand Factor, Factor XIII, fibrinogen and fibronectin.

For clarity it is suggested that claim 17 is amended to read, "A concentrate [[of at least one]] comprising a cryoprecipitable protein comprising [[the]] a stabilizing and solubilizing formulation in combination with [[at least one]] the protein prepared by the process [[according to]] of claim 1.

For clarity it is suggested that claim 18 is amended to read, "[[A]] The concentrate [[according to]] of claim 17 [[intended to-for therapeutic use]] wherein said concentrate is used as a therapeutic.

For clarity it is suggested that claim 19 is amended to read, "[[A]] The concentrate [[according to]] of claim 17, [[presenting a]] comprising filterability of about 2 ml/cm^2 on a filter with a porosity of 0.20 ± 0.02 um.

Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 14-18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Branovic et al., (Applied Biochemistry and Biotechnology, vol. 69, 1998, pages 99-111.

The claimed invention is directed to a method to obtain cryoprecipitable proteins using a virus inactivation step, a freeze dried form and stabilizing/solubilizing formulation (see claim 1 for example) and further comprising FVIII, VWF, FXIII, fibrinogen and fibronectin as the proteins (see claim 16, for example).

Branovic et al., disclose a FVIII wherein a double virus inactivation step is utilized to isolate from cryoprecipitate. The Branovic et al., reference discloses that "viral

inactivation was performed by combination of S/D treatment and heating of final freeze-dried product..." (see page 99 of the reference). Branovic et al., discloses the use of stabilizers (page 103 Figure 1 flow chart) and uses an anhydrous form of trisodium citrate (Figure 1 flow chart pages 102-104). The method of Branovic et al., uses filtration and solvent detergent (see Figure 1).The reference discloses purification of a concentrate (see pages 100-101). Therefore, the limitations of the claims are met by the reference.

Response to Arguments

5. Applicant's comments have been considered in full. Objections/Rejections withdrawn from the record will not be discussed herein and applicant's comments pertaining to the same is considered moot and will not be discussed. Note that the 102 rejection of record remains. Applicant's state that the reference cited teaches the use of sucrose and the instant specification discloses that carbohydrates such as sucrose should be avoided from the formulation. This argument is not persuasive as limitations of the specification cannot be read into the claims and the methods recite the language of "comprising" thus there can be additional method steps including "using sucrose" before or after items (a), (b) and (c) of the claims. Therefore, the reference of record remains relevant. Note that objections have been made over the instant claims to put them in better form.

Conclusion

6. No claims are presently allowable.

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652